

Evaluating a delegated allied health assistant-led model for procedural care for children with cancer: A non-inferiority trial design

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Abstract

This study evaluated a delegated Allied Health Assistant (AHA)-led model of care for reducing procedural anxiety to workforce optimisation. The primary research question was in children with cancer undergoing routine medical procedures, is an AHA-led model of care delivered by an appropriately trained AHA following OT clinical screening, non-inferior to an OT-led model for reducing child anxiety?

A single-centre non-inferiority trial was conducted within a tertiary paediatric oncology service (September 2024-September 2025). Outcomes were assessed at baseline and three months later. Child procedural anxiety was measured using the Procedural Anxiety subscale of the Pediatric Quality of Life Inventory, and distress using the Distress Thermometer.

One hundred and ten children participated (mean age 7 years 10 months; range 1–16 years). Most (72%) had a diagnosis of leukaemia or lymphoma. Common procedural demands included anaesthesia (77%) and port access (57%). Screening resulted in approximately a 2:1 allocation ratio, with 63.6% of participants receiving OT-led care and 26.5% managed through the delegated AHA-led pathway. Delegated AHA-led care was non-inferior to OT-led care in reducing procedural anxiety, as the lower bound of the 95% confidence interval for the interaction term (-8.72) exceeded the pre-specified non-inferiority margin (-75).

With appropriate training, supervision, and clinical governance, delegating children with non-clinical distress to AHA-led procedural support represents a sustainable approach to service delivery that maintains high-quality, patient-centred care and offers practical guidance for allied health leadership and workforce planning.

INTRODUCTION

Procedural anxiety is characterised by fear, anxiety, and anticipatory worry related to healthcare procedures. This anxiety is frequently linked to previous negative experiences, resulting in recurring cycles of fear and pain further exacerbating distress [1]. Severe levels of procedural anxiety and distress may result in the requirement of sedative pre-medications and/or physical restraint, as well as postponement or abandonment of procedures [2]. Such outcomes can have persisting negative effects, with lifelong impacts on healthcare utilisation, as well as increased risk of side-effects from medication, delayed treatment and trauma [3].

A paediatric cancer diagnosis can be considered a rare occurrence, yet its impact places a profound physical, emotional and social burden on affected children and their families [4]. In 2024–2025, approximately 750–760 children aged 0–14 were estimated to be diagnosed with cancer each year in Australia [5]. Statistics indicate an upward trend in prevalence of childhood cancer diagnosis, with the incidence rate of childhood cancer in Australia increasing by 35% over the past four decades [5]. Children with cancer are subjected to frequent and often invasive medical procedures to treat the disease – some of which include surgeries, intravenous chemotherapy and radiation [6]. The psychosocial standards of

care in paediatric oncology indicate that youth with cancer should receive developmentally appropriate preparatory information about invasive medical procedures; and that all youth should receive psychological intervention for invasive medical procedures [7].

Procedural care describes an approach and group of interventions that a health professional uses to help, improve or restore a child's ability to engage in their medical procedures [8]. For over two decades, the reduction of procedural anxiety for children has been a clinical imperative [9]. Children with cancer consistently report higher pain from their medical procedures than the cancer itself [10]. Untreated procedural anxiety and distress can lead to several immediate (i.e., reduced treatment adherence, traumatic stress symptoms, increased pain and anxiety) and longer-term issues (i.e., ongoing post-traumatic stress symptoms and reduced healthcare utilisation as an adult) [11, 12]. Without effective procedural care, children can become overwhelmed with anxiety about being in hospital and/or medical procedures, which can negatively impact their post-treatment recovery [13]. This has significant impact on patient flow related to additional staffing and time requirements to complete procedures.

Concerns have been raised regarding the sustainability of the paediatric oncology workforce, particularly among allied health professionals working in emotionally demanding, high intensity care environments [14]. It is widely agreed that health care environments pose high risk of staff burnout, which can have serious consequences for patient and staff safety [15]. The long-term nature of relationships with children and their families through cancer treatment results in heightened risk of emotional stress [16, 17], with almost one third (31%) of staff working in Queensland oncology centres experiencing burnout [18].

The Queensland Children's Hospital (Brisbane, Australia) Occupational Therapy (OT) Oncology procedural care role was established in 2022. Routine service data collected 2022–2024 identified a tripling of occasions of service to support paediatric oncology patients with procedural care interventions. An algorithm was established whereby baseline screening was completed within one week from diagnosis, allocating patients to universal, targeted or specialist pathways of procedural care supports to manage workload. Despite positive outcomes, sustainability and access was a concern due to the high-volume clinical load serviced predominantly by a single clinician.

Allied health assistants (AHAs) contribute to the provision of health care by delivering clinical and health related tasks, consistent with their training, qualifications and scope of practice, that support high quality, integrated care across a range of service settings [19]. AHAs undertake clinical tasks related to the treatment of patients that are delegated by an allied health practitioner [20]). These roles support hospital and health services to allocate resources effectively to deliver high value, efficient and person-centred services [21], although are frequently not optimally utilised [22]. Professional reluctance to delegate clinical tasks, limitations in training and the time required for the AHA to reach effective skill level are contributing factors [23]. A systematic review and meta-analysis identified when appropriate delegation models are in place, there was no deterioration in patient outcomes when AHA delivered

therapy substituted allied health practitioner therapy – with increased therapy doses improving patient and organisational outcomes [24].

While literature exists to support the use of AHA delegation for clinical tasks [19, 20], no specific research has been conducted which explores the role of AHA delegation in procedural care services. Therefore, the aim of this project was to evaluate the relative effectiveness of a delegated AHA-led model in reducing child anxiety (primary outcome) and child distress (secondary outcome) using a recently established model of care in the study setting. The objective was to compare the change in (a) child anxiety and (b) child distress from baseline screening to 3 month follow-up. The clinical hypothesis was that the change in child anxiety in patients delegated to an AHA-led model will be non-inferior to the change observed by patients primarily seen by an OT-led model.

METHODS

Study Design and Setting

A non-inferiority trial was completed in a single-centre study within the Paediatric Oncology service at the Queensland Children's Hospital from September 2024 until September 2025. The protocol was ethically approved by the Children's Hospital and Health service (HREC/24/QCHQ/1107327). The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist for cohort studies was used to guide manuscript preparation.

The Oncology Services Group at Queensland Children's Hospital is the sole tertiary referral centre for paediatric oncology in Queensland and Northern New South Wales, managing approximately 200–250 new cases annually [25]. Within the study setting, an established procedural care team including an OT (0.4 full time equivalent), Senior OT (0.6 full time equivalent) and an AHA (0.8 full time equivalent) provided procedural preparation and support to the oncology patient population. Prior to study commencement, the AHA role (i.e., standard care) within the oncology procedural care team was to provide supplementary sessions as delegated by an OT for patients with targeted and specialist levels of support needs. For example, delegation by an OT for medical play sessions and/or graded desensitisation. In the expanded scope model, the AHA completed training as outlined in a Clinical Task Instruction (see Appendix 1) to implement an AHA-led model of procedural support for children who scored below clinical distress levels at screening (typically within one week of admission). The clinical task instruction training package took the AHA approximately 4 hours to complete, supported by monthly clinical supervision with the senior OT. Throughout the study, AHAs maintained this expanded scope (in addition to providing their previous standard care for patients in the OT-led model).

Participants and recruitment

From September 2024 – June 2025, children aged 1–18 with a new oncology diagnosis (or relapsed diagnosis) were eligible for inclusion. Participants aged younger than 12 months were not invited to

participate due to their developmental age and stage.

Outcome Measures

Child anxiety was measured using the procedural anxiety subtest of the Pediatric Quality of Life Inventory (PedQL) [26]. The PedQL is a validated measure, with published normative mean (SD) score of 60 (33) in children with cancer. In a population group drawn from the study setting, these scores were demonstrated to not significantly change over an 8-week period [27]. The three PedsQL 'Procedural anxiety' scale items were collected for each participant at baseline screening and 3-month follow-up assessments. As per the assessment scoring guidelines, Likert-scale responses were transformed to a numerical scale of 0-100 (i.e. 'Almost always' resulted in a score of 0, 'Almost never' resulted in a score of 100) [28]. The mean score was calculated for the three items. The outcome for each participant was calculated as the difference between the mean score at baseline and the mean score at 3-month follow-up assessment.

Child distress was measured using the patient distress thermometer (DT), a validated measure of emotional distress for parents of children with cancer [29]. Scores range from 0 (no distress) to 10 (extreme distress). A score of 4 has been established as a cut-off score for identifying clinical distress [30]. The DT has been found to have good internal consistency (0.61–0.91) [31].

Data collection

Participants were invited to complete baseline screening with an OT, which informed their allocation to a pathway (AH-led or OT-led) for their procedural care interventions. Baseline screening assessments were completed by an OT (N = 3) working in Oncology Procedural Care. When completing the screening, the OT utilised clinical judgement in identifying who was best to answer the questions, pending the child's age and developmental stage. Questions were answered by either the parent/caregiver or the child in collaboration with their parent/caregiver. Patients were allocated to either a delegated AHA-led or an OT-led model of care based on their distress thermometer scores (see Fig. 1).

Patients reporting a distress score of 4 and above were allocated to a targeted / specialist model of procedural care led by an OT. Where clinically indicated, these targeted / specialist models of care also included supplementary delegated sessions (focused on age-appropriate procedural education) with the AHA to increase the therapy dose for these patients, who required more intensive support. At 3-months post diagnosis, participants were approached by an OT to complete follow-up assessment. Screening and follow-up assessments were completed in-person with patients and families, with results entered manually into Microsoft Excel™ (version 2508).

Data analysis

Non-inferiority using a Linear Mixed Model (LMM) approach was used to assess the main hypothesis of non-inferiority of AHA, considering both time points (baseline and 3-month follow up). LMMs were fitted with the patient’s reported level of distress scores and quality of life scales as the dependent variable, including fixed effects for group (AHA vs OT), time (baseline vs follow-up) and the group-by-time interaction, and a random intercept for each participant. Non-inferiority was confirmed if the lower bound of the two-sided 95% confidence interval for the interaction term was greater than the pre-specified non-inferiority margin [32] of 25%, with a null mean difference of 25 points on the 0-100 scale for PedsQL (corresponding to a one level change on the likert question response). Descriptive statistics were collected for the following variables: age, diagnosis and regular procedures. Categorical outcomes were reported using counts and corresponding percentages. Continuous outcomes were reported using mean (SD), median (IQR) and range, where appropriate.

RESULTS

There were 110 participants recruited (see Table 1), with an age range of 1 to 16 years and mean age of 7 years,10 months. The majority (72%) of patients recruited had a diagnosis of blood cancer (i.e. leukaemia or lymphoma), with their most common procedural demands including port access (57%).

Table 1
Demographics of participants

Characteristic	Category		
Age (years)	Mean (SD)	7.79 (5.01)	
	Median (Q1, Q3)	7.0 (3.0, 13.0)	
	Range (Min–Max)	1.0–16.0	
		N	%/Value
Diagnosis	Liquid / BMT	77	71.96
	Solid tumour	30	28.04
Regular procedures	General anaesthetics	87	77.27
	Port access	63	57.27
	Finger pricks / venipuncture	51	46.36
	Nasogastric tube insertions	39	35.45
	CVL dressing change	35	31.81
	PICC dressing change	31	28.18
	Sub-cutaneous injection	18	16.36
	Radiation	5	4.50

Participant screening assessments resulted in approximately a 2:1 recruitment for OT: AHA group, with 63.55% of patients allocated to an OT-led model for targeted/specialist care and 26.45% allocated to the delegated AHA-led model (universal pathway). The median (interquartile range), range for patients allocated to the *AHA-led model* for occasions of service were 3 (1,4), 0–6 and 1 (1,2), 1–17 for AHA and OT respectively. Occasions of service for patients in the *OT –led model* were 5 (3,8), 1–20 and 4 (0,4), 0–15 for OT and AHA respectively.

Throughout the 3-month period, 35% (n = 10), of the patients allocated to AHA required an unplanned OT review due to escalation in their distress. These patients required further clinical assessment and decision making, therefore extending beyond the scope of an AHA. Escalations in these patient’s distress were most often attributed to complications experienced in their treatment, resulting in new or unexpected procedural demands, combined also with a reduced capacity to cope (child and/or caregivers).

Overall Quality of Life Scale

As presented in Table 2, delegated AHA-led model of care was non-inferior to OT-led model of care for reducing child anxiety (i.e., lower bound of the 95% CI for the interaction term was estimated to be -8.718, which is greater than the pre-specified non-inferiority margin of -75).

Table 2
Non-inferiority using a linear mixed model approach

(Intercept)	Estimate	Lower 95% CI	Upper 95% CI	p-value
	201.282	180.864	221.7	< 0.001
Treatment Group: Occupational Therapy	-103.414	-129.027	-77.802	< 0.001
Time: T2	23.718	-3.539	50.975	0.091
Treatment Group x Time	25.473	-8.718	59.665	0.147

The AHA-led model showed higher values than OT-led at both time points (Fig. 2), supporting non-inferiority.

DISCUSSION

This study has supported the hypothesis that a delegated AHA-led model is non-inferior in reducing child anxiety, thus supporting the sustainability of a specialist procedural care service in paediatric oncology.

Existing research consistently suggests that for AHAs to successfully deliver high-quality care, delegation models require clear criteria to ensure clinically delegated tasks are consistent with the AHA’s training, qualifications and scope of practice [19]. The underlying proposed mechanism of action for the AHA model of care in the current study was that children with a low distress score have characteristics

of autonomy and successful utilisation of coping strategies, making them less likely to require frequent or intensive procedural care support. Overall, the findings of this study support a delegated AHA-led model of procedural care when appropriate delegation models are in place (including the safety net of OT review in emergent circumstances that exceed AHA scope of practice).

The delegated AHA-led model within the procedural care team was identified as not only a strategy for caseload sustainability but also improved the access to procedural support for oncology patients. Due to increasing level of demand for the OT in supporting patients with complex and severe procedural care needs, the expanded scope role of AHA in supporting patients with more 'universal' procedural care needs meant that these patients and families received supports that otherwise not likely to be available. Therefore, the expanded scope role meant the oncology service could deliver procedural support aligned to best practice guidance that *all* paediatric oncology patients have access to timely, developmentally appropriate procedural preparation and support across the continuum of care [33].

Research suggests that AHA's are generally underutilised in health services. Stute et al. [22] identified contributing factors include reluctance of professionals to delegate clinical tasks. The presence of a clear delegation model reduced this risk in the current study and established expanded AHA scope as part of usual business. Further contributing factors to under-utilisation was the time frame and support required for an AHA staff member to reach effective skill level to competently deliver delegated task. This risk within the project was mitigated by the presence of clinical task instructions, a structured on-boarding practice and repetition in clinical demands from a 4-hour training session and regular [monthly] clinical supervision (from the senior procedural care OT).

A challenge identified throughout the study was the efficacy of attempting to quantify a child's experiences of anxiety and distress. These challenges were related to definition, proxy reporting (due to a child's age) and timing of screening. Masse [34] discusses psychological distress and anxiety to involve subjective, contextual and culturally mediated experiences. Qualitative methods of assessment allow clinicians to capture meaning, narrative and lived experience, while quantitative measures provide risk of reification or turning a complex emotional experience into an oversimplified number.

Throughout the study duration, participants and families often struggled to distinguish overall distress (emotional, existential, psychosocial) from procedural-specific distress (i.e. anxiety and distress related specifically to a hospital procedure). For example, specifically at time of baseline screening (typically within one week of presentation), participants often rated levels of procedural anxiety and distress at a level that were not consistent with the clinician's observations about a participant's coping and management during procedures. This may be a result of overarching grief, distress and coping / adjustment to a new oncology diagnosis and 'fears of the unknown' that impacted on clinical responses. Wong and colleagues [35] identified that currently there is a notable gap in availability of standardised frameworks integrating pain, anxiety and satisfaction measures, while prioritising child perspectives, with most current approaches overlooking emotional and psychological dimensions. Further, as identified from a systematic review [36], the psycho-oncology field lacks a holistic and homogeneous

definition of distress, thus it is difficult for clinicians and researchers to separate global emotional distress from specific components (such as procedural) distress.

The National Cancer Institute [37] have identified that anxiety and distress in cancer patients appear at various times during diagnosis, treatment and recurrence i.e., distress fluctuates and does not remain stable. The Adjustment to Cancer: Anxiety and Distress (PDQ®) explicitly describe distress as dynamic and tied to multiple points across the cancer trajectory [37]. Because the emotional burden shifts with new medical events, decisions, and symptoms, measuring distress at only one time is unlikely to capture a patient's true or ongoing level of psychosocial strain. Therefore, there is no single optimal time point at which distress should be measured, because levels may rise or fall depending on disease stage, treatment changes, symptoms, or new information [37]. While initial meetings and baseline procedural distress screening was aimed to be completed in a timely manner post diagnosis to support a proactive approach to procedural care, it is identified that this immediate period post diagnosis of acute stress, shock and heightened emotions likely contributed to challenges differentiating between global distress and specifically procedural distress. In addition, the regimen of follow-up assessment at 3-months post diagnosis meant that pending the child's diagnosis, the stage of their treatment journey and subsequently their procedural demands were not consistent. For example, 3-months post diagnosis for some patients fell within a less intensive block of their therapy, with fewer hospital visits and fewer procedures resulting in overall perceptions of reduced anxiety and distress. Meanwhile, for other patients, 3-months post diagnosis fell in a significant time-point of their treatment – for example many orthopaedic-oncology patients participated in follow-up assessments just days after intense and often life-altering surgeries (for example, limb amputations or complex reconstructive procedures requiring PICU admissions).

However, findings from the study do have several implications for clinical practice, workforce planning and service delivery. The use of quantitative outcome measures in isolation meant that not all aspects of the patient's circumstances were considered (for example, where they were at in their treatment journeys, how families interpreted and considered 'procedural distress', the extent of their treatment demands). For this reason, future clinical practice in assessment of procedural anxiety and distress should aim to include a high value conversation alongside patient reported outcome measures to ensure that measures of progress are appropriately understood [38] when completing screening.

Strengths and limitations

A key strength of this study is that the proposed model of care was not only developed but also implemented and tested in a real-world clinical setting. Much health services research remains largely conceptual or theoretical, with limited translation into routine practice [39]. Attrition in the current study occurred only due to death or withdrawal from the service (due to relocation), resulting in near-complete follow-up (97.2%) minimising the risk of selection bias.

A limitation of this study is that the model of care incorporated AHA delegation within the OT-led model, rather than a clear contrast between exclusively OT-led care or exclusively delegated AHA-led care. While this introduces a methodological limitation within the non-inferiority trial design, it is a pragmatic examination of real-world clinical practice involving delegation. This approach enabled optimal use of the AHA scope of practice and aligned with the study's primary workforce objective of supporting service sustainability.

Additionally, due to the varying ages of participants, there was variation as to who completed surveys (e.g., the child, the parent, or both in collaboration). Assessing clinicians often identified discrepancies between reported levels of distress and anxiety when assessments were answered by the child and the parent – with parents subjectively noted to rate their child as more distressed than the child rated themselves. This observation is consistent with findings that highlighted systematic inaccuracies in parent reporting, with parent-child agreement on anxiety, depression and distress only being rated as *fair*, with parents consistently rating their children as more distressed than the child's own report [40].

Future research could explore the application of this screening-led delegation model of care within broader chronic illness populations, where long-term functional support and workforce sustainability are ongoing challenges (e.g., bone marrow transplant services).

Overall, findings of this study indicate that the use of a delegated AHA-led model is supported as an appropriate strategy to promote workforce sustainability and optimise use of the health practitioner workforce, whilst maintaining best care and best value. By embedding appropriate delegation, supported by training, onboarding, and governance, the model demonstrates how services can work towards a value-based system that supports healthcare sustainability while maintaining high-quality, patient-centred, safe, and reliable care. These findings highlight the effectiveness of delegated models when appropriately supported and provide practical insights to inform Allied Health governance processes and strategic leadership at a local service level.

Declarations

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Author Contribution:

Emma Mitchell: Conceptualisation, validation, formal analysis, investigation, resources, data curation, writing – original draft, review and editing, visualisation, project administration, funding acquisition

Amanda Carter: Conceptualisation, writing – review & editing, supervision

William Perez: Methodology, validation, formal analysis

Megan Simons: Conceptualisation, methodology, validation, writing – review & editing, supervision, project administration, funding acquisition

Declaration of Conflicting Interest

My Room children's cancer charity funded the procedural care Occupational Therapy and Allied Health Assistant positions but had no input into research design or manuscript preparation.

Funding Statement

This research received funding from the Queensland Health Health Practitioner Research Scheme (HPRS) for financial year 2024-2025 for EM (nee Kerr) and MS (clinical backfill). There were no other supports received from any funding agency in the public, commercial or not-for-profit sectors.

Ethical Approval and Informed Consent

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Ethical approval was obtained from the Children's Health Queensland Hospital and Health Service (HREC/24/QCHQ/1107327), a Site-Specific Agreement (SSA) was obtained (SSA/2024/QCHQ/107327). This research was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP).

Written informed consent was obtained from the parents and health professionals.

Data Availability

The data that support the findings of this study are available on request from the corresponding author and with appropriate permission from Children's Health Queensland Hospital and Health Services Human Research and Ethics Committee (HREC). Data may be made available upon reasonable request where that request aligns with the conditions of the original ethical approval. Additional ethical approval may be required to access the data.

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Figures



Figure 1

Procedural care allocation pathway and data collection timepoints

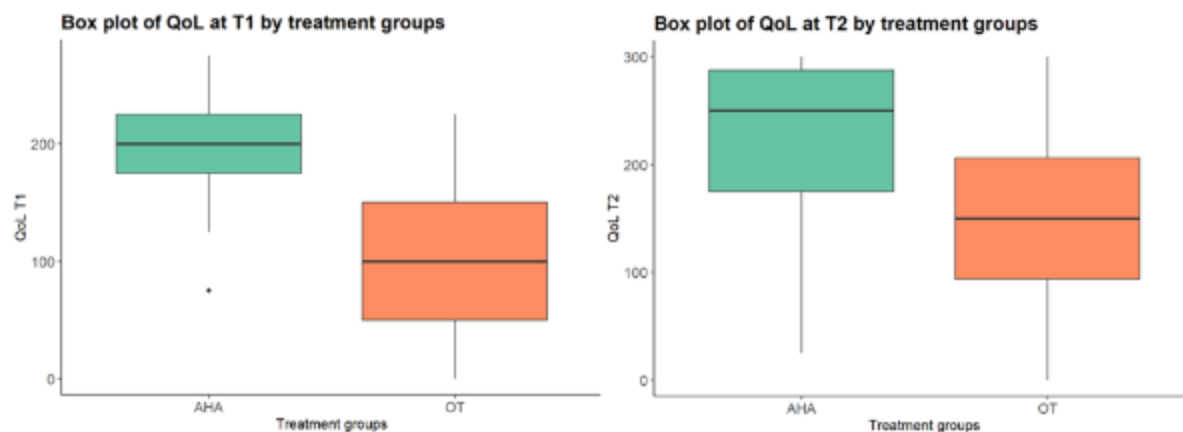


Figure 2

Box plot of Quality of Life at baseline and 3-month follow up

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Appendix1ClinicalTaskInstructionforAlliedHealthAssistant.docx](#)